SEP - 4 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Alpha-1-antitrypsin method for ADVIA® 1650™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K031857

1. Intended Use

The *Bayer ADVIA Chemistry* Alpha-1-antitrypsin assay is an *in vitro* diagnostic device intended to quantitatively measure Alpha-1-antitrypsin concentration in human serum and plasma on the ADVIA® Chemistry system. Measurement of alpha-1-antitrypsin levels aid in the diagnosis of juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Roche Alpha-1-antitrypsin	1557599	1355279

3. Device / Method

Product Name	Reagent REF (part #)	Calibrator REF (part #)
Bayer ADVIA® Chemistry Alpha-1-antitrypsin	06921866 (B01-4834-01)	07711199 (B03-4845-01)

4. Performance:

A. Imprecision

ADVIA 1650	
Level (ug/dL)	Within-run CV(%)
91.83	1.1
188.39	0.83
346.99	0.85

Roche	
Level (ug/dL)	Within-run CV(%)
67.5	3.9
496.8	0.7
574.8	7.33

B. Correlation (Y=ADVIA 1650, X=comparison system)

Specimen Type	Comparison System (x)	N	Regression Equation	Syx	r	Sample Range mg/dL
Serum	Hitachi AAT	44	Y = 0.94x + 13.1	20.6	0.965	42.8 – 258.9

C. Interfering Substances

Alpha-1-antitrypsin (ug/dL)	Interferent	Interferent (mg/dL)	Alpha-1-antitrypsin with interferent (mg/dL)	% Recovery
200.5	Hemoglobin	1000	220.3	109.88%
201.6	Bilirubin conj	25	207.3	102.83%
207.3	Bilirubin unconj	25	204.9	98.84%
204.5	Intralipid	125	223	109.05%
252.8	TRIG concentrate	187.5	268.9	106.37%

D. Analytical Range

Serum/Plasma: 5.37 mg/dL to AAT concentration in highest calibrator (typically 510 mg/dL).

6/5/03

Date

Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, New York 10591-5097

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Re: k031857
Trade/Device Name: Alpha-1-antitrypsin Assay for the ADVIA® Chemistry System
Regulation Number: 21 CFR § 866.5130
Regulation Name: Alpha-1-antitrypsin immunological test system
Regulatory Class: II
Product Code: DEM
Dated: August 12, 2003
Received: August 13, 2003

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number: K031857

Device Name: Alpha-1-antitrypsin Assay for the ADVIA® Chemistry System

Indications for Use:
The *Bayer ADVIA Chemistry* Alpha-1-antitrypsin method is an *in vitro* diagnostic device intended to quantitatively measure alpha-1-antitrypsin levels in human serum and plasma. Such measurements are used in the diagnosis of juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031857